make it absolutely clear claim 1 has been amended.

Regarding claim 5 no changes were made. The term "include" in claim 5 is used as a substitute for "comprise". It means the same thing as "comprise". Claim 5 depends on claim 4, which recites "synthetic gestogens". Claim 5 states that the synthetic gestogens are limited to including medroxyprogesterone acetate.

For the foregoing reasons and because of the changes in claim 1 withdrawal of the objection to the wording of amended claims 1 and 5 is respectfully requested.

Claims 1 to 7 were rejected under 35 U.S.C. 103 (a) as obvious over Embase Abstract -272 in view of WPIDS abstracts -924 and -225 and all the references of record in U.S. Patent 08/738,314.

The references, DE 42 24 534 A1 and DE 41 04 385 C1, were of record in U.S. Patent Application 08/738,314. These DE references disclosed closest prior art methods to the methods of claims 1 to 7.

Applicants have tested an example of the method of applicants' claim 1 and the corresponding closest-prior-art method of these two DE references and have measured the intercyclic bleeding occurring in both methods. The results appear in a signed Declaration (which is a copy of a Declaration filed in 08/728,314) in accompanying this amendment.

The results in the Declaration show that the method claim in applicants' claimed 1 is more effective in preventing conception than that of the two DE

references, but at the same time significantly reduces intercyclic bleeding. These results also provided the basis for allowing claims in Ser.No. 08/738,314.

Regarding the reasons for rejection in the Office Action, the applicants have already admitted in the background section of the above-identified U.S. Patent Application that both two-stage and three-stage contraceptive preparations are known.

The problem that the invention of the applicants solves is to provide an effective contraceptive preparation with at least reduced side effects, which contains natural estrogens instead of ethinyl estradiol. The preparations including ethinyl estradiol had a number of disadvantages as explained in the background section, but until the applicants' work no effective preparation based on natural estrogens had been made. Previous attempts failed because the preparations with the natural estrogen caused too much intracyclic bleeding.

Thus the closest prior art should be limited to preparations containing natural estrogens. The Embase abstract -272 and WPIDS abstract –924 teach contraceptive preparations that are not limited to natural estrogens, and thus are not particularly relevant to the problem that applicants' are trying to solve. These references do not suggest or disclose contraceptive preparations that are limited to containing natural estrogens. Exemplary two-stage preparations of the DE references tested in the Declaration contained estradiol valerate, which is a natural estrogen used in the exemplary three-stage preparations of the invention tested in the Declaration. Bleeding produced by the preparation of the claimed invention was found to be significantly less than that of the prior art.

For the foregoing reasons and because of the comparative experimental results filed in the accompanying Declaration, withdrawal of the rejection of claims 1 to 7 under 35 U.S.C. 103 (a) as obvious over Embase Abstract -272 in view of WPIDS abstracts -924 and -225 and all the references of record in U.S. Patent Application 08/738,314 is respectfully requested.

Claims 1 to 7 were rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claims 1 and 3 to 7 of U.S. Patent 6,133,251.

There are many differences between the subject matter of claim 1 of the above-identified U.S. Patent Application and the subject matter of claim 1 of the U.S. Patent. Claim 1 of the above-identified U.S. Patent Application is boarder. Applicants desire broader patent claim coverage and seek that broader coverage in the present application.

First, the first stage daily dosages of the present claim 1 do not necessarily each contain the same amount of natural estrogen: each must include an effective amount. The same is true of the other stages. Also the second stage daily dosages are not broken into two subgroups with different dosage amounts. In addition, the effective ingredients of the second stage daily dosages are not necessarily limited to the natural estrogen and the gestogen, but could include another active ingredient, especially a synthetic estrogen.

Thus several modifications of the claims of the U.S. Patent are required to obtain the inventive preparation as claimed in applicants' claim 1.

It is respectfully submitted that these modifications are not suggested in the art and that the claims 1 to 7 of the above-identified U.S. Patent Application are patentably distinguished from the claims 1 and 3 to 7 of U.S. Patent 6,133,251.

For the foregoing reasons withdrawal of the rejection of claims 1 to 7 under the judicially created doctrine of obviousness-type double patenting over claims 1 and 3 to 7 of U.S. Patent 6,133,251 is respectfully requested.

APPENDIX SHOWING THE CHANGES MADE IN CLAIM 1 TO OVERCOME THE INDEFINITENESS REJECTION

1(amended). A combination preparation for contraception comprising from 2 to 4 first stage daily dosage portions, each [including] of said first stage daily dosage portions containing an effective amount of at least one natural estrogen as sole active ingredient [,]; from 16 to 22 second stage daily dosage portions, each [including] of said second stage daily dosage portions containing an effective amount of a combination of at least one natural estrogen and at least one natural or synthetic gestogen as active ingredient; from 2 to 4 third stage daily dosage portions, each of said third stage daily dosage portions containing [including] an effective amount of at least one natural estrogen as sole active ingredient; and from 2 to 4 additional stage daily dosage portions, each of said additional stage daily dosage portions containing a pharmaceutically acceptable placebo.

Should the Examiner require or consider it advisable that the specification, claims and/or drawing be further amended or corrected in formal respects to put this case in condition for final allowance, then it is requested that such amendments or corrections be carried out by Examiner's Amendment and the case passed to issue. Any costs involved should be charged to the deposit account of the undersigned (No. 19-4675). Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing the case to allowance, he or she is invited to telephone the undersigned at 1-631-549 4700.

In view of the foregoing, favorable allowance is respectfully solicited.

Respectfully submitted,

Michael J. Striker,

Attorney for the Applicants

Reg. No. 27,233